

training for a period of time sufficient to increase sodium excretion levels.” (see page 3, paragraph 1 of point 4).

Applicants have amended Claim 1 to recite the embodiment stated by the Examiner in point 4 as being enabled. Therefore, it is requested that the rejection be withdrawn in light of this amendment.

Claim 1 has been rejected under 35 U.S.C. § 112, second paragraph, as indefinite. The Examiner has taken the position that Claim 1 is indefinite because Claim 1 recites “an II genotype for an angiotensin converting enzyme gene.” Applicants have amended the claim so that it is directed towards the human ACE (angiotensin converting enzyme) gene. Additionally, Applicants have attached to this Response an attachment differentiating between the II and ID genotypes. This information is available in GenBank at Accession No. x62855. Therefore, it is requested that the rejection be withdrawn in view of the amendment made to Claim 1.

Claim 1 has been rejected as anticipated by Hagberg et al (WO 99/45383) (hereinafter “Hagberg”). The Examiner has taken the position that Hagberg teaches a method that can be employed to reduce the blood pressure of hypertensive individuals and that the method taught in Hagberg is similar to that of the claimed invention. The Examiner has noted that the process taught by Hagberg includes the steps of identifying subjects who are in need of a reduction in blood pressure and who have an angiotensin converting enzyme gene II genotype, and engaging those subjects in moderate exercise. The Examiner has also noted that the definition listed in Hagberg for

“moderate exercise” is similar to the definition for the presently claimed “limited exercise training.”

The Examiner has advanced that while the present invention is directed towards the end of “increasing sodium excretion levels in a hypertensive subject,” the present invention is otherwise identical to that of the Hagberg reference. Therefore, the Examiner has taken the position that the performance of the Hagberg process would inherently result in an increase of sodium excretion levels in the subject. Therefore, the Examiner has taken the position that the increased sodium excretion claimed in the present invention is a previously unrecognized benefit that would necessarily result from the exercise of the Hagberg method.

It is submitted that this rejection is not well taken. In order for Hagberg to properly anticipate the present application, Hagberg must teach every aspect of the claimed invention. It is noted that the preamble of Claim 1 (as amended in this Response) states that Claim 1 is directed towards a method of increasing sodium excretion levels in a hypertensive human subject. As MPEP section 2111.01 states “[i]f the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is necessary to give life, meaning, and vitality to the claim, then the claim preamble should be construed as if in the balance of the claim.” (*quoting Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298 (Fed. Cir. 1999)).

It is submitted that the claim preamble supplies a limitation, that of increasing sodium excretion. Further, Claim 1 ends with the requirement that the limited exercise training be for a period of time sufficient to increase sodium excretion levels. Hagberg

does not teach this aspect of the invention. Hagberg does not even discuss sodium excretion levels. Therefore, it is submitted that Hagberg cannot anticipate the invention.

As for the inherency rejection, it is submitted that no evidence has been provided that the use of the Hagberg process would necessarily increase the sodium excretion levels of the subject. That is, MPEP section 2112 requires that an inherency rejection be supported by proof that the allegedly inherent property would necessarily flow from the teachings of the cited reference. However, no evidence has been provided by the Examiner that the time period sufficient for reducing blood pressure would also be sufficient for increasing sodium excretion. Therefore, it is requested that the rejection be withdrawn as MPEP section 2112 states that the “mere fact that a certain thing may result from a given set of circumstances is not sufficient” to support an inherency rejection. Therefore, it is requested that the rejection be withdrawn for this reason.

Finally, regarding new Claim 2, it is submitted that Hagberg is insufficient to anticipate Claim 2 for the reasons stated above and because Hagberg does not teach the step conducting a test to determine whether sodium excretion levels have increased as a result of the exercise. Therefore, it is submitted that Hagberg is deficient as a reference against new Claim 2 for these reasons.

The present application has been rejected on the judicially created doctrine of obviousness-type double patenting in view of Claim 8 of Hagberg et al. (U.S. Patent 6,399,306) (hereinafter “Hagberg II”).

The Examiner has taken the position that Claim 8 of Hagberg II renders the claims of the present invention not patentably distinct from Hagberg II. It is noted that


the Examiner has used arguments in defense of this rejection that are identical to those used in the anticipation rejection. It is submitted, then, that the double patenting rejection is not well taken for the same reasons set forth above. That is, Claim 8 of Hagberg II does not teach the increase of sodium excretion, which is a limitation of the claimed invention. Absent a teaching of this element in Hagberg II, or a showing that it would necessarily follow from the Hagberg II process, it is submitted that this rejection is not well taken.

As for new Claim 2, it is submitted that Claim 8 of Hagberg II does not teach a specific step directed to determining whether sodium excretion levels have increased as a result of the exercise. Therefore, it is submitted that Claim 2 is patentably distinct from Claim 8 of Hagberg II.

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In the event this paper is not being timely filed, the applicants respectfully petition for an appropriate extension of time. Any fees for such an extension together with any additional fees may be charged to Counsel's Deposit Account 01-2300, referencing Attorney Docket No. 108172-00072.

Respectfully submitted,


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Enclosures: Marked Up Copy of the Claims
Attachment

MARKED UP COPY OF THE CLAIMS

1. (Amended) A method of increasing sodium excretion levels in a hypertensive human subject, the method comprising:

identifying a hypertensive human subject having [an] a II genotype for [an] human angiotensin converting enzyme gene (ACE), wherein the human subject is in need of increased sodium excretion levels; [and]

engaging the human subject in limited exercise training for a period of time sufficient to increase sodium excretion levels in the human subject.



Below is a portion of ACE Intron 16. The insertion, which gives rise to the I allele is shown in CAPS. When this sequence is deleted, the D allele results.

gtgagccgagatggcgccactgcactccagcctgggcaacagagtgagaccctg
tctcagaaagaaaaaaaaaaaaaaaaaggagaggagagagactcaagcacgcccct
cacaggactgctgaggccctgcaggtgtctgcagcatgtgccaggccggggac
tctgtaagccactgctggagaccactcccatacctttctcccatttctctagacctgctg
cctATACAGTCACTTTTTTTTTTTTTTTTTTTGAGACGGAG
TCTCGCTCTGTCGCCCAGGCTGGAGTGCAGTGGCG
GGATCTCGGCTCACTGCAACGTCCGCCTCCCGGGT
TCACGCCATTCTCCTGCCTCAGCCTCCCAAGTAGC
TGGGACCACAGCGCCCGCCACTACGCCCGGCTAA
TTTTTTGTATTTTATAGTAGAGACGGGGTTTCACCGT
TTAGCCGGGATGGTCTCGATCTCCTGACCTCGTG
ATCCGCCCCGCCTCGGCCTCCCAAAGTGCTGGGATT
ACAGGCGTGatacagtcacttttatgtggttcgccaattttattccagctctga
aattctctgagctccccttacaagcagaggtgagctaagggctggagctcaagcca
ttcaaccccctaccag